October 9, 2025

Shenzhen Jianchao Intelligent Technology Co., LTD
% Riley Chen
RA Specialist
Feiying Drug & Medical Consulting Technical Service Group
Rm 2401 Zhenye International Business Center, No. 3101-90
Qianhai Road
Shenzhen, Guangdong 518052
China

Re: K252553
Trade/Device Name: Facial & Body Beauty Device (INIA-BD001, INIA-BD002, INIA-BD003, INIA-BD004, F2C15, F3222 Pro, F5516, F3606, F2210 Pro, F5808, INIA-ED001, INIA-ED002, INIA-BLD001, E1507)
Regulation Number: 21 CFR 882.5890
Regulation Name: Transcutaneous Electrical Nerve Stimulator For Pain Relief
Regulatory Class: Class II
Product Code: NFO
Dated: August 12, 2025
Received: August 13, 2025

Dear Riley Chen:

We have reviewed your section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of

Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the

Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Tushar Bansal -S

Tushar Bansal, PhD
Acting Assistant Director, Acute Injury Devices Team
DHT5B: Division of Neuromodulation and
Physical Medicine Devices
OHT5: Office of Neurological and
Physical Medicine Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K252553

Please provide the device trade name(s).

Facial & Body Beauty Device (INIA-BD001, INIA-BD002, INIA-BD003, INIA-BD004, F2C15, F3222 Pro, F5516, F3606, F2210 Pro, F5808, INIA-ED001, INIA-ED002, INIA-BLD001, E1507)

Please provide your Indications for Use below.

Facial & Body Beauty Device is a hand-held device for over-the counter aesthetic purposes.
The Microcurrent stimulation mode is indicated for facial skin stimulation and body skin stimulation.

Please select the types of uses (select one or both, as applicable).

- ☐ Prescription Use (Part 21 CFR 801 Subpart D)
- ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

510(k) Summary - K252553

"510(k) Summary" as required by 21 CFR Part 807.92.

I. Submitter

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Date of preparation: 2025-10-09

II. Device Information

Name of Device: Facial & Body Beauty Device
Models: INIA-BD001, INIA-BD002, INIA-BD003, INIA-BD004, F2C15, F3222 Pro, F5516, F3606, F2210 Pro, F5808, INIA-ED001, INIA-ED002, INIA-BLD001, E1507
Common or Usual Name: Stimulator, Transcutaneous Electrical, Aesthetic Purposes
Regulation Name: Transcutaneous electrical nerve stimulator for pain relief
Regulatory Class: II
Product Code: NFO
Regulation Number: 21 CFR 882.5890

III. Predicate Device

Predicate Device	Manufacturer	510(k) Number	Product code
BEAGANK 4T PLUS	Belega Inc.	K233010	NFO
Microcurrent Facial Device Models: CEC101, EE0101, EEI101	Shenzhen Dachi communication Co.,Ltd.	K244004	NFO

IV. Device Description

Facial & Body Beauty Device is portable, non-sterile and reusable device, which is designed to achieve the aesthetic effect. The device mainly consists of a main unit and charging cable, and it is supplied by internal rechargeable lithium battery, which can be recharged by external charger through the provided charging cable, but the device can not be used when charging.

To use the device, user should place the electrode head on the face and body. The device will automatically shut down after treatment time is over.

V. Indications for Use

Facial & Body Beauty Device is a hand-held device for over-the counter aesthetic purposes.

The Microcurrent stimulation mode is indicated for facial skin stimulation and body skin stimulation.

VI. Comparison of Technological Characteristics With the Predicate Device

The Facial & Body Beauty Device has the same intended use as the predicate devices. The technological characteristics, features, specifications, design and intended use are similar to the predicate devices. Any minor differences between the subject device and the listed predicate devices do no raise any issues of safety or efficacy. Performance data supports that the device is safe and as effective as the predicate devices for its intended use.

Comparison Elements	**Subject Device**		**Primary predicate device**	**Secondary predicate device**	**Remark**
K number	**K252553**		**K233010**	**K244004**	**/**
Trade name/ Model	Facial & Body Beauty Device, Model: INIA-BD001, INIA-BD002, INIA-BD003, INIA-BD004, F2C15, F3222 Pro, F5516, F3606, F2210 Pro, F5808	Facial & Body Beauty Device, Model: INIA-ED001, INIA-ED002, INIA-BLD001, E1507	BEAGANK 4T PLUS	Microcurrent Facial Device Models: CEC101, EE0101, EEI101	/
Device class	Class II	Class II	Class II	Class II	Same
Product code	NFO	NFO	NFO	NFO	Same
Indication for use/Intended use	Facial & Body Beauty Device is a hand-held device for over-the counter aesthetic purposes. The Microcurrent stimulation mode is indicated for facial skin stimulation and body skin stimulation.	Facial & Body Beauty Device is a hand-held device for over-the counter aesthetic purposes. The Microcurrent stimulation mode is indicated for facial skin stimulation and body skin stimulation.	The BEAGANK 4T PLUS is a handheld portable device for over-the-counter aesthetic use including facial and neck stimulation or body skin stimulation.	CEC101 and EE0101: Microcurrent Facial Device is intended for facial stimulation for over-the-counter aesthetic use. EEI101: Microcurrent Facial Device is intended for facial, neck and body skin stimulation for over-the-counter aesthetic use.	Same
OTC or prescription	OTC	OTC	OTC	OTC	Same
Treatment site	Face and body	Face and body	Face, neck and body	EEI101: Facial, neck and body skin CEC101: Facial skin EE0101: Facial skin	Same
Power Supply	Internal Li-ion battery: 3.7Vd.c. 1100mAh	Internal Li-ion battery: 3.7Vd.c. 300mAh	Internal rechargeable Lithium-ion battery	Input:5V 1A; Output:3.7V CEC101: 3.7V/2600mAh EE0101: 3.7V/800mAh EEI101: 3.7V/2600mAh	Different **Note 1**

Comparison Elements		**Subject Device**		**Primary predicate device**	**Secondary predicate device**	**Remark**
K number		**K252553**		**K233010**	**K244004**	**/**
Handheld design		Yes	Yes	Yes	Yes	Same
Software/ Firmware/ Microprocessor Control?		Yes	Yes	Yes	Yes	Same
Average DC current through electrodes when device is on but no pulses are being applied		0A (< 1μA)	0A (< 1μA)	< 1μA	< 1μA	Same
Output channels		1 output channel	1 output channel	1 output channel	1 output channel	Same
Regulated Current or Regulated Voltage?		Regulated voltage	Regulated voltage	Voltage Control	Voltage Control	Same
Automatic Overload Trip?		No	No	Not required due to circuit design	No	Same
Automatic Shut Off		Yes	Yes	Yes	Yes	Same
User Override Control?		Yes	Yes	Yes	Yes	Same
Indicator	On/Off Status	Yes	Yes	Not publicly available	Yes	Same
	Low Battery	Yes	Yes	Yes	Yes	Same
	Voltage/ Current Level	Yes	Yes	Not publicly available	Yes	Same
Waveform Type		Bi-phase square-wave pulse	Bi-phase square-wave pulse	Rectangle, biphasic asymmetric	Bi-phase square-wave pulse	Same

Comparison Elements	**Subject Device**		**Primary predicate device**	**Secondary predicate device**	**Remark**
K number	**K252553**		**K233010**	**K244004**	**/**
Maximum Output Voltage	Mode 1: 16V@500Ω; 21V@2KΩ; 22.5V@10KΩ Mode 2: 15V@500Ω; 22V@2KΩ; 23V@10KΩ	Mode 1: 16V@500Ω; 18V@2KΩ; 22.5V@10KΩ Mode 2: 16V@500Ω; 18V@2KΩ; 20V@10KΩ	Mode 1: 0.12V@ 500 Ω 0.51V@ 2K Ω 1.83V@ 10K Ω Mode 2: 0.11V@ 500 Ω 0.50V@ 2K Ω 1.87V@ 10K Ω Mode 3: 16.6V@ 500 Ω 21.0V@ 2K Ω 22.5V@ 10K Ω Mode 4: 15.3V@ 500 Ω 21.2V@ 2K Ω 22.9V@ 10K Ω	CEC101: 3.77 V±10% @ 500 Ω 11.85 V±10% @ 2K Ω 33.2 V±10% @ 10K Ω EE0101: 3.57 V±10%@ 500 Ω 11.25 V±10% @ 2K Ω 31.25 V±10% @ 10K Ω EEI101: 3.54 V±10%@ 500 Ω 12.3 V±10% @ 2K Ω 34 V±10% @ 10K Ω	Similar **Note 2**
Maximum Output Current	Mode 1: 32mA@500Ω; 10.5mA@2KΩ; 2.25mA@10KΩ Mode 2: 30mA@500Ω; 11mA@2KΩ; 2.3mA@10KΩ	Mode 1: 32mA@500Ω; 9mA@2KΩ; 2.25mA@10KΩ Mode 2: 32mA@500Ω; 9mA@2KΩ; 2mA@10KΩ	Mode 1: 0.19mA@ 500 Ω 0.18mA@ 2K Ω 0.16mA@ 10K Ω Mode 2: 0.45mA@ 500 Ω 0.39mA@ 2K Ω 0.24mA@ 10K Ω Mode 3: 30.8mA@ 500 Ω 8.52mA@ 2K Ω 2.26mA@ 10K Ω Mode 4: 31.4mA@ 500 Ω	CEC101: 7.54 mA±10% @ 500 Ω 5.93 mA±10% @ 2K Ω 3.32 mA±10% @ 10K Ω EE0101: 7.14 mA±10%@ 500 Ω 5.63 mA±10%@ 2K Ω 3.13 mA±10%@ 10K Ω EEI101: 7.08 mA±10%@ 500 Ω 6.15 mA±10%@ 2K Ω 3.4 mA±10%@ 10K Ω	Similar **Note 2**

Comparison Elements	**Subject Device**		**Primary predicate device**	**Secondary predicate device**	**Remark**
K number	**K252553**		**K233010**	**K244004**	**/**
			8.60mA@ 2K Ω 2.15mA@ 10K Ω		
Pulse Period (Pulse Width)	Mode 1: P:84μs, N:84μs Mode 2: P:112μs, N:76μs	80μs	Mode 1: 130μs Mode 2: 130μs Mode 3: 80μs Mode 4: 92μs	CEC101: 174μs EE0101: 174μs EEI101: 145μs	Different **Note 2**
Output Frequency (Hz)	Mode 1: 3.6kHz Mode 2: 1.6kHz	Mode 1: 3.4kHz Mode 2: 1.4kHz	Mode 1: 3.80kHz Mode 2: 3.80kHz Mode 3: 3.65kHz Mode 4: 1.64kHz	40Hz, 97.8Hz	Similar **Note 2**
Net Charge	0 μC @ 500Ω	0 μC @ 500Ω	Mode 1: 0.025μC@500Ω Mode 2: 0.025μC@500Ω Mode 3: -1.3μC @ 500Ω Mode 4: 0μC @ 500Ω	0 μC @ 500Ω	Same
Maximum current density	Mode 1: 0.099mA/cm^2 Mode 2: 0.11mA/cm^2	Mode 1: 0.20mA/cm^2 Mode 2: 0.18mA/cm^2	Mode 1: 0.15~1.36 mA/cm^2@ 500Ω Mode 2: 0.10~3.21 mA/cm^2 @500Ω Mode 3: 4.26~220 mA/cm^2 @500Ω Mode 4: 3.13~224.3 mA/cm^2 @500Ω	CEC101: 0.09mA/cm^2@500Ω EE0101: 0.45mA/cm^2@500Ω EEI101: 0.15mA/cm^2@500Ω	Similar **Note 2**
Maximum Power Density	Mode 1: 0.026mW/cm^2 Mode 2: 0.031mW/cm^2	Mode 1: 0.026mW/cm^2 Mode 2: 0.024mW/cm^2	Mode 1: 8.51~11.39 μW/cm^2@500Ω Mode 2: 17.46~33.87 μW/cm^2@500Ω Mode 3: 1.124~106.6 mW/cm^2@500Ω Mode 4: 0.56~51.78 mW/cm^2@500Ω	CEC101: 0.045mW/cm^2@500Ω EE0101: 0.21mW/cm^2@500Ω EEI101: 0.065mW/cm^2@500Ω	Similar **Note 2**

Comparison Elements	**Subject Device**		**Primary predicate device**	**Secondary predicate device**	**Remark**
K number	**K252553**		**K233010**	**K244004**	/
Treatment recommendation	10 minutes	10 minutes	5 minutes	CEC101: 3-8 minutes EE0101: 5-8 minutes EEI101: 5-8 minutes	Similar **Note 3**
Main Materials	PC, PC+ABS, Zinc alloy	PC, ABS, Stainless Steel, Zinc alloy, Silica gel	ABS	ABS, Stainless steel	Different, but solved by biocompatibility tests
Dimension	52(L)×48(W)×188(H)mm	164.5(L)×31(W)×17.3(H) mm	Not publicly available	CEC101:193.68*68*60mm EE0101: 90*65*39mm EEI101: 202.6*69.32*62mm	Different **Note 4**
Net Weight	220g	95.3g	136g	CEC101: 266g EE0101: 120g EEI101: 230g	Different **Note 4**

Comparison in Detail(s):

Note 1:

Although the "Power source" is different from the primary predicate device, they are both powered by the internal lithium battery. The lithium battery of the subject device complies with the IEC 62133-2 standard, and the device complies with IEC 60601-1 and IEC 60601-1-2 requirements, so this difference will not raise any safety or effectiveness issue.

Note 2:

- The "Maximum Output Voltage" and "Maximum Output Current" of the subject device (both model INIA-BD001 and INIA-ED001) are very close to that of the mode 3 and mode 4 of the primary predicate device, thought there is still a little difference, the setting of the subject device is within the maximum and minimum range of predicate devices;

- The "Pulse Width" and "Output frequency" of subject device (both model INIA-BD001 and INIA-ED001) are similar with the settings of mode 3 and mode 4 of the primary predicate device, thought there is still a little difference, the setting of the subject device is within the

maximum and minimum range of predicate devices;

- Although the "Maximum Current Density" and "Maximum Power Density" of subject device are little different from the primary predicate device, their are in the maximum and minimum range of predicate devices;

We also have tested the product waveform parameters according to FDA guidance and tested the device according to the requirements of IEC 60601-2-10, the tests are all passed, so these differences do not raise safety and effectiveness problems.

Note 3:

The treatment recommendation of time of the subject device is 10 minutes, it is longer than that of the primary predicate device, but is very close to the predicate device 1, which is 8 minutes. The subject device complies with IEC 60601-1 and IEC 60601-2-10 requirements, so this difference will not raise any safety or effectiveness issue.

Note 4:

Though the dimension and weight of the subject device are different from the predicate devices, this difference is insignificant and do not raise any safety or effectiveness problems.

VII. Non-Clinical Testing

The following performance data were provided in support of the substantial equivalence determination.

1) Electrical Safety and EMC Safety

- IEC 60601-1 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-2 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
- IEC 60601-1-11 Medical Electrical Equipment –Part 1-11: General Requirements for Basic Safety and Essential Performance –Collateral Standard: Requirements for Medical Electrical Equipment and Medical Electrical Systems Used in the Home Healthcare Environment
- IEC 60601-2-10 Medical electrical equipment - Part 2-10: Particular requirements for the basic safety and essential performance of nerve and muscle stimulators
- IEC 62133-2 Secondary cells and batteries containing alkaline or other non-acid electrolytes - Safety requirements for portable sealed secondary cells, and for batteries made from them, for use in portable applications - Part 2: Lithium systems

2) Biocompatibility Safety

- ISO 10993-5: 2009, Biological evaluation of medical devices – Par t 5: Tests for in vitro cytotoxicity
- ISO 10993-10: 2021, Biological evaluation of medical devices - Part 10: Tests for skin sensitization
- ISO 10993-23: 2021, Biological evaluation of medical devices - Part 23: Tests for irritation

VIII. Clinical Testing

Not applicable.

IX. Conclusions

Based on the above analysis and non-clinical tests performed, it can be concluded that the subject device is as safe, as effective, and performs as well as the legally marketed predicate devices.